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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/778,548	02/07/2001	David M. Lubman	UM-06102	5017

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EXAMINER	
DEJONG, ERIC S	
ART UNIT	**PAPER NUMBER**
1631	

DATE MAILED: 12/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/778,548	LUBMAN ET AL.	
	Examiner	Art Unit	
	Eric S. DeJong	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 October 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16,18,20,33-35,39-43,48,50,73-77,80-86 and 91* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16,18,20,33-35,39-43,48,50,73-77,80-86 and 91* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED OFFICE ACTION

Specification

The objection of the disclosure as containing an embedded hyperlink is withdrawn in view of the amendment to the specification filed by applicants on 10/14/2005.

Claim Objections

Applicant is advised that should claims 34 and 35 be found allowable, claim 35 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). This objection is newly applied.

Claim Rejections - 35 USC § 112, First Paragraph

The rejection of claims 1-16, 18 and 20 under 35 USC §112, first paragraph, for failing to comply with the written description requirement is withdrawn in view of amendments made to the instant claims.

Claim Rejections - 35 USC § 112, Second Paragraph

The rejection of claims 1-16, 18, 20, 34, and 44 under 35 USC §112, second paragraph, as being indefinite is withdrawn in view of amendments made to the instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-15, 18, 20, 33, 35, 39-43, 48, 50, 73-77, 80-86, and 91are rejected under 35 U.S.C. 103(a) as being unpatentable over Lagu in view of Holloway et al. in view of Hatt et al. and as further evidenced by Opiteck et al. (citation 2 of IDS filed on 22 November 2004), Davidsson et al. (citation 92 of IDS filed on 14 October 2003), and Klimczak et al. This rejection is newly applied.

The instant claims are drawn to methods of separating proteins comprising providing a first separating apparatus that separates proteins based on a first physical property, a second apparatus that separates proteins based on a second physical property, a mass spectroscopy apparatus, a plurality of plurality of proteins wherein the sample further comprises a buffer containing a compound of the formula n-octyl C_6-C_{12} glycopyranoside, further treating said sample with said first and second separation apparatuses to produce a separated protein sample, directly feeding the separated protein sample into said mass spectrometry apparatus and mass spectrally analyzing at least a portion of the separated protein sample to characterized protein mass. In some embodiments the method further comprises the use of an automated sample handling device comprising a switchable multi-channel valve.

Lagu sets forth a review of capillary electrophoresis and related techniques used in various high-throughput and automated methods for the separation and analysis of recombinant proteins recovered from cell lysates. Lagu provides for methods

comprising a first separation of sample by application of either capillary gel electrophoresis or capillary isoelectric focusing, a second separation step of HPLC, and followed by an analytical step of the output from the HPLC step by mass spectroscopy (see especially Lagu, page 3148, column 2, lines 18-46). Further, Lagu provides an example of the use of a six-port multi-valve system for directing the flow of analytes from one separation apparatus to another (see especially Lagu, page 3149, column 1, line 11 through column 2, line 9). Figures 1-7 of Lagu further illustrate schematic representations of the physical properties of various proteins measured and analyzed by the disclosed methodologies.

While Lagu does teach the above disclosed method comprising an generic analytical step of performing mass spectral analysis, Lagu does not explicitly teach that the mass spectral analysis may be performed by either electro spray or time-of-flight mass spectroscopic techniques as recited in instant claims 8, 39, and 82. Opiteck et al. and Davidsson et al. are relied upon to provide evidence that both electrospray and time-of-flight techniques are commonly relied upon in the art for protein mass spectral analysis (See especially Opiteck et al., page 1523 and Davidsson et al., page 644).

Further, while Lagu does not explicitly teach that phospohylated proteins can be suitably resolved with the disclosed separation and analysis techniques, Klimczak et al. is relied upon to provide evidence that phosphorylated proteins may be reliably separated and characterized via electrophoretic, HPLC, and mass spectroscopic techniques (see especially, Klimczak et al., Abstract and page 911).

While Lagu sets forth the application of capillary electrophoresis related method in conjunction with HPLC and mass spectroscopic techniques as described above, Lagu does not fairly teach or suggest the use of buffers containing n-octyl glucopyranoside compounds as instantly claimed.

Holloway et al. shows in the abstract, page 13, and in figure 3b that inclusion of n-octyl glucopyranoside in the buffer used for isoelectric focusing reduces streaking of samples.

Hatt et al. shows in the abstract and page 340 that octyl beta glucopyranoside is compatible with analysis of protein samples by mass spectroscopy.

Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ the separation and analysis techniques, as taught by Lagu and further evidenced by Opiteck et al., Davidsson et al. and Klimczak et al., in combination with a buffer comprising octyl beta-glucopyranoside because Holloway et al. shows that use of the nonionic detergent octyl beta-glucopyranoside improves resolution in isoelectric focusing and Hatt et al. shows that octyl beta-glucopyranoside does not interfere with subsequent analysis of the sample by mass spectroscopy.

Provisional Obviousness-Type Double Patenting

Regarding use of the specification in obviousness-type double patenting rejections, the MPEP states in section 804:

When considering whether the invention defined in a claim of an application is an obvious variation of the invention defined in the claim of a patent, the disclosure of the patent may not be used as prior art. This does not mean that one is precluded from all use of the patent disclosure.

The specification can always be used as a dictionary to learn the meaning of a term in the patent claim. In re Boylan, 392 F.2d 1017, 157 USPQ 370 (CCPA 1968). Further, those portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent. In re Vogel, 422 F.2d 438, 441-42, 164 USPQ 619, 622 (CCPA 1970). The court in Vogel recognized "that it is most difficult, if not meaningless, to try to say what is or is not an obvious variation of a claim," but that one can judge whether or not the invention claimed in an application is an obvious variation of an embodiment disclosed in the patent which provides support for the patent claim. According to the court, one must first "determine how much of the patent disclosure pertains to the invention claimed in the patent" because only "[t]his portion of the specification supports the patent claims and may be considered." The court pointed out that "this use of the disclosure is not in contravention of the cases forbidding its use as prior art, nor is it applying the patent as a reference under 35 U.S.C. 103, since only the disclosure of the invention claimed in the patent may be examined."

Claims 1-8, 33-35, 39, 48, and 50 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 18,

20-24, 27-33, 35, and 37-47 of copending Application No. 09/968,930. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are drawn to a method of characterizing proteins specifically requiring a buffer comprising a compound of the formula n-octyl C_6-C_{12} glycopyranoside and an analytical step of performing mass spectroscopic analysis, where as the copending claims of Application No. 09/968,930 are drawn to a method which is generic to the use of a buffer comprising a compound of the formula n-octyl C_6-C_{12} glycopyranoside as well as comprising an analytical step of mass spectroscopy. However, the disclosure of the copending application specifically teaches preferred embodiments of the claimed method using a buffer comprising a compound of the formula n-octyl C_6-C_{12} glycopyranoside as well as comprising an analytical step of mass spectroscopy (see for example the specification of copending Application No. 09/968,930; page 3, line 25 through, page 4, line 4 and page 5, lines 19-21).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (f) he did not himself invent the subject matter sought to be patented.

Claims 1-8, 33-35, 39, 48, and 50 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter. This rejection is newly applied.

For the reasons discussed above, it is apparent that copending Application No. 09/968,930 contains subject matter in the claims that is not patentably distinct from instant claims. Because the inventive entity of copending Application 09/968,930 is different from the instant application, a rejection is appropriate under 35 U.S.C. § 102(f). This rejection could be overcome by amendment of the appropriate claims so that the claims are patentably distinct, or by filing a declaration stating the inventive entity for the commonly claimed subject matter is identical.

Conclusion

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (571) 272-0549.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. DeJong whose telephone number is (571) 272-6099. The examiner can normally be reached on 8:30AM-5:00PM.
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D. can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For all other customer support, please call the USPTO Call Center at (800) 786-9199.

EDJ EDJ

4 December 2005

JOHN S. BRUSCA, PH.D
PRIMARY EXAMINER